Buprenorphine/Naloxone Pediatric Ingestion: Exposure Rates Differ between Film and Tablet Formulations

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Background

Unintentional exposures to potent opioid medications by young children can cause severe illness or death.

An oral film formulation of buprenorphine/naloxone was introduced for sale in the US in September 2010. A previously published report showed differences in the pediatric exposure rates between the buprenorphine tablet, buprenorphine/naloxone tablet, and buprenorphine/naloxone film formulations, but at the time of the previous study only 18 months of exposure data were available for the combination film.

The purpose of this study it to evaluate whether differences in the rates of unintentional pediatric exposures to buprenorphine and buprenorphine/naloxone formulations are stable over time.

Data Source

The Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System Poison Center program collects data about opioid medication exposures, including patient age, reason for exposure, specific formulation, and medical outcome.

In the first quarter of 2013, 49 poison centers covering 92.6% of the US population provided data to the RADARS System.

Prescription fulfillment data were obtained from IMS Health Solutions.

Complete RADARS System information is available at www.radars.org.

Methods

RADARS System Poison Center program case counts and medical outcomes for unintentional exposures to buprenorphine/naloxone tablets and oral film among children aged 0 – 5 years from October 2009 to March 2013 were analyzed.

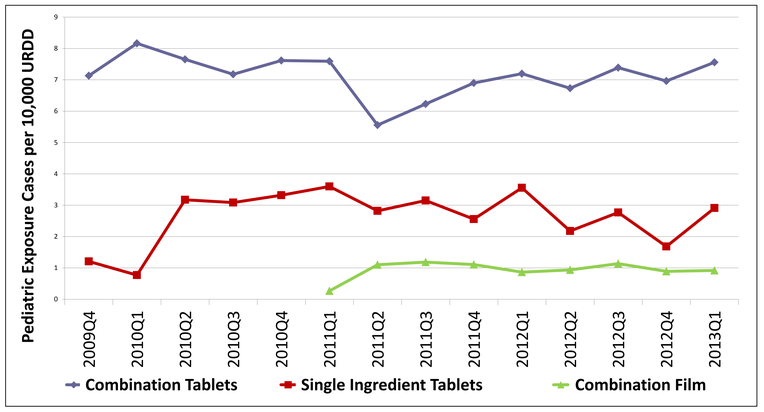
To account for drug availability, rates were standardized using unique recipients of a dispensed drug (URDD) per year-quarter.

Negative binomial regression was used to estimate rates and confidence intervals. Average quarterly rates were calculated from 2011/Q2 – 2013/Q1.

Results

1,695 reports of unintentional exposure to sublingual buprenorphine products were analyzed.

For the overall study period and for each individual quarter, the rate of exposures to combination tablets exceeded the rates for single ingredient tablets and combination film. These relationships remain consistent over 27 months of measurement.



	Rate *Exposures per 10,000 URDD*	95% CI	Rate Ratio	95% CI	Significance
Combination Tablets	7.0	6.6 – 7.3	7.6	6.7 – 8.6	P < 0.0001
Single Ingredient Tablets	2.8	2.4 – 3.2	3.1	2.6 – 3.7	P < 0.0001
Combination Film	0.9	0.8 – 1.0	*Reference*		

Limitations

Because of voluntary reporting, not all exposure cases are known to poison centers.

Formulation identification and reason for exposure are based on information provided by the caller and cannot be verified independently.

These data do not include generic buprenorphine/naloxone tablets, which were introduced in February, 2013.

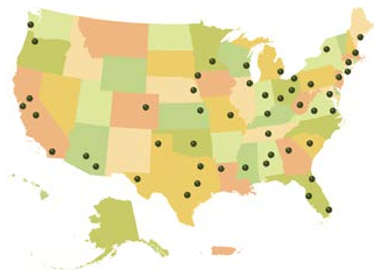
Conclusions

The rate of unintentional exposures to buprenorphine/naloxone sublingual film by young children remains significantly less than the rate of exposure to buprenorphine/naloxone or buprenorphine single ingredient tablets.

Participating Poison Centers and Investigators

Alabama Poison Center: Dorough L
Arizona Poison and Drug Information Center: Boesen K
Banner Good Samaritan Poison and Drug Information Center: Stevens D
Blue Ridge Poison Center: Holstege CP, Vakkakanka PV, Wenger, KL
California Poison Control System: Alsop JA
Central Ohio Poison Center: Spiller HA, Huffman RM, Casavant MJ
Central Texas Poison Center: Baker SD
Children's Hospital of Michigan: Smolinske S, Price P
Cincinnati Drug and Poison Information Center: Yin S, Pierce B
Connecticut Poison Control Center: McKay C, Hart K
Florida Poison Information Center – Jacksonville: Schauben JL, Sollee D
Florida Poison Information Center – Miami: Bernstein J, Weisman RS
Florida Poison Information Center – Tampa: Kimball T, Aleguas A
Georgia Poison Center: Geller RJ, Jones A, Lopez G, Hon S
Hennepin Regional Poison Center: Anderson D, Lintner C
Illinois Poison Center: DesLauries C, Kubic A
Indiana Poison Center: Mowry JB
Iowa Statewide Poison Control Center: Bottei E, Kalin L, Ringling S
Kentucky Regional Poison Center: Runge H
Long Island Regional Poison and Drug Information Center*: Caraccio T, Jao D
Louisiana Poison Center: Ryan M
Maryland Poison Center: Doyon S
Massachusetts/Rhode Island Poison Center: Burns Ewald M, Sheroff A
Mississippi Poison Control Center: Cox R, Parker C
Missouri Regional Poison Center: Weber J, Enders S, Odom C
Nebraska Regional Poison Center: Jacobitz K, Rasmussen M
New Jersey Poison Information and Education System: Ruck B, Marcus S, Rego R
New York City Poison Control Center: Hoffman R, Mercurio-Zappala M
North Texas Poison Center: Abron D, Uzoegwu L, Gardner M
Northern New England Poison Center: Simone KE, Bubar J
Northern Ohio Poison Center: Quang L
Oklahoma Poison Control Center: McGoodwin L, Schaeffer S
Oregon Poison Center: Giffin S, McKeown N
Palmetto Poison Center: Michels J
Pittsburgh Poison Center: Krenzelok E, Kurta D
Regional Poison Control Center of Alabama: Liebelt E, Slattery A, Brooks S, Phillips J
Rocky Mountain Poison & Drug Center: Dart RC
South Texas Poison Center: Fernández MC, Cobb DB, Villarreal CL
Tennessee Poison Center: Kumar S, Seger D
Texas Panhandle Poison Center: Jaramillo J, Rivers R
The Ruth A. Lawrence Poison & Drug Information Center
Serving Finger Lakes*: Barton N, McFarland S, Rekkerth D
The University of Kansas Hospital Poison Control Center: Lowry J, Oller L
Upstate New York Poison Center: Cantor R, Stork C, Caliva M
Virginia Poison Center: Rose SR, Waring E
Washington Poison Center: Martin T, Chew A, Von Derau K, Gibson J
West Texas Regional Poison Center: Torres O, Baeza S, Anzures J
West Virginia Poison Center: Scharman EJ
Western New York Poison Center*: Joshi P
Wisconsin Poison Center: Kostic M

** Center closed December 2010.*



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